

**510(k) SUMMARY: CORRIDOR™ Fixation System**

FEB - 6 2009

**Company:** Globus Medical Inc.  
2560 General Armistead Ave.  
Audubon, PA 19403  
(610) 415-9000

**Contact:** Kelly J. Baker, Ph.D  
Director, Clinical Affairs & Regulatory

**Device Name:** CORRIDOR™ Fixation System

**Classification:** Product Code MRW. Class II.

**Predicate(s):** Legally marketed predicated devices

**Device Description:**

The CORRIDOR™ Fixation System consists of screws designed to compact juxtaposed facet articular processes to enhance spinal fusion. The screws are available partially threaded or fully threaded, cannulated or non-cannulated, and in various diameters and lengths to accommodate patient anatomy. The CORRIDOR™ Fixation System screws are fabricated from medical grade titanium alloy as specified in ASTM F136 and F1295. Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be used in the same construct as stainless steel implants.

**Intended Use:**

The CORRIDOR™ Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5mm and 4.0mm screws and from L1 to S1 for 4.5mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle.

The CORRIDOR™ Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

**Basis for Substantial Equivalence:**

CORRIDOR™ Fixation System is similar in terms of indications, design, materials, and performance, to currently marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 6 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Globus Medical, Inc.  
% Dr. Kelly J. Baker  
2560 General Armistead Ave., Valley Forge  
Audubon, PA 19403

Re: K083442  
Trade/Device Name: Corridor Fixation System  
Regulation Number: Unclassified  
Regulation Name: N/A  
Regulatory Class: Unclassified  
Product Code: MRW  
Dated: November 19, 2008  
Received: November 20, 2008

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 – Dr. Kelly J. Baker

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K083442

Device Name: CORRIDOR™ Fixation System

### Indications:

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Prescription Use X  
(Per 21 CFR §801.109)

OR

Over-The-Counter Use     

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number 2/6/04